IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

DEBRA PARKS, et al.	*	
Plaintiffs	*	
v.	*	
		CIVIL CASE NO.: RBD-06-2411
ALPHARMA, INC., et al.	*	
Defendants	*	

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PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF OPPOSITITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

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Plaintiff, Debra Parks, by her attorneys, Robert C. Morgan, Gilbert F. Shelsby, and Morgan Carlo Downs & Everton, P.A., hereby files this Memorandum in Support of Plaintiff's Opposition to Defendant Alpharma, Inc.'s Motion for Summary Judgment, and says:

INTRODUCTION

This is a case about a pharmaceutical corporation, Defendant Alpharma, Inc., that went astray in the 2000s in illegally marketing its pain medication product, KADIAN®, through false representations about its effectiveness and risks. Plaintiff Debra Parks, who Alpharma employed from approximately 2002 to July 2006 as a sales representative, unfortunately found herself in the middle of not one, but **five** different fraudulent schemes during her employment at Alpharma. Those schemes were: (1) Alpharma's decision to hide or "bury" the results of a clinical study, which a physician, Michael S. Kaplan, M.D., Ph.D., performed starting in approximately August 2004 pursuant to a contract with Alpharma; (2) an illegal marketing campaign also involving Dr. Kaplan, where Alpharma sales representatives instructed physicians on an "off-label" method of converting patients to Kadian; (3) a presentation in February 2006 also involving Dr. Kaplan where Alpharma proposed that Dr. Kaplan give an off-label promotion of Kadian to Coventry

Healthcare; (4) Alpharma's false promotion of Kadian as being safe when co-ingested with alcohol; and (5) the illegal promotion of Kadian as being less prone to abuse and diversion compared to other pain medications.

As will be demonstrated more fully below, Mrs. Parks complained to her superiors at Alpharma about all of those fraudulent schemes and Alpharma fired her for doing so in violation of 31 U.S.C. § 3730(h).

STATEMENT OF FACTS

A. Procedural History and Allegations in Complaint

In September 2006, Mrs. Parks commenced the present False Claims Act ("FCA") action in this Court against Alpharma under seal. Mrs. Parks thereafter amended her Complaint on two occasions. On March 10, 2010, Plaintiffs, Debra Parks and the United States of America, executed a settlement agreement with Alpharma and Defendant King Pharmaceuticals, Inc., whereby Alpharma will pay the U.S. and several State governments approximately **$51.4 million ($51,400,000)** in compromise of the disputed claims raised in the FCA case. The Settlement Agreement states that it is not a concession by the United States that its claims were not well-founded.

On March 16, 2010, this Court granted the United States' Notice of Election to Intervene and partially unsealed the case as to allegations against Alpharma, Inc., Alpharma Branded Products Division, Inc., Faulding Laboratories, and Purepac Pharmaceutical Company, as set forth in the unsealed redacted Second Amended Complaint filed on March 16, 2010.

The redacted Second Amended Complaint alleges that Alpharma fraudulently marketed its morphine-based drug "Kadian" by (i) paying illegal kickbacks to providers to induce them to

prescribe Kadian, both on-label and off-label; and (ii) making false representations about Kadian's effectiveness and risks to aggressively and improperly promote both on-label and off-label uses of the drug. The redacted Second Amended Complaint also alleges that as a result of these illegal inducements and fraudulent marketing practices, Alpharma defrauded the United States and the Plaintiff States of many tens of millions of dollars.

Kadian is a slow-release form of morphine that is approved for use in treatment of patients with chronic pain. Kadian is marketed in 10 mg, 20 mg, 30 mg, 50 mg, 60 mg and 100 mg capsules. Alpharma marketed Kadian as different and superior to other opioids – such as OxyContin, Vicodin, Avinza, Percocet and Lortabs – because Kadian has a time release mechanism providing for "dosing flexibility" and "is the only brand in its category that can be dosed either once or twice daily." *See* Second Amended Complaint, ¶¶ 45-46.

Mrs. Parks worked for Alpharma from 2002 through July 2006. Mrs. Parks alleges in the FCA action that she was wrongfully terminated from her employment at Alpharma due to her protected activity under the FCA in violation of 31 U.S.C. § 3730(h). On April 20, 2010, this Court entered an Order approving a Stipulation of Dismissal filed by the United States, Mrs. Parks, and Alpharma, pursuant to which the United States and Mrs. Parks dismissed all of the claims against Alpharma in the FCA action, with the exception of Mrs. Parks' Section 3730(h) claim. Mrs. Parks' Section 3730(h) claim, therefore, is the sole remaining claim against Alpharma in this action.[1]

[1] Per an agreement between counsel for Mrs. Parks and Alpharma, Mrs. Parks's Section 3730(h) claim against Alpharma Branded Products Division, Inc., Faulding Laboratories and Purepac Pharmaceutical Co. will be dismissed by stipulation. Alpharma Branded Products Division, Inc.

B. History of Mrs. Parks's Employment at Alpharma

Mrs. Parks (55 years old) is married and is the mother of two daughters. During her employment at Alpharma from 2002-July 2006, she lived in Reisterstown, Maryland. She began working as a territory sales manager at Alpharma in May 2002 in the Mid-Atlantic District (Maryland and Delaware). Exhibit 1 (Deposition of Debra Parks), pp. 11, 26, 31. During her employment at Alpharma, Mrs. Parks became an extremely successful sales representative and she consistently ranked in the top five percent of Alpharma sales representatives nationally. *Id.* at p. 42. Mrs. Parks earned numerous awards for her work at Alpharma. For example, in 2002, Mrs. Parks earned the award of "Representative of the Quarter" for the Fourth Quarter in 2002, meaning she ranked number one among district sales representatives for sales volume in that quarter. In 2003, Mrs. Parks earned the awards of "Representative of the Quarter" in both the Third and Fourth Quarters of that year. *See* Exhibit 2 (Affidavit of Debra Parks), ¶ 1.

In 2004, Mrs. Parks earned the award of "Sales Representative of the Year," meaning she was the number one ranking sales representative nationally within Alpharma, which had approximately 170 sales representatives at that time. By becoming the sales representative of the year in 2004, Mrs. Parks also became a member of the "Circle of Excellence" for 2004, which is an honor recognizing Alpharma's top 12 sales representatives nationally. Mrs. Parks also earned the award of "Representative of the Quarter" in the First and Second Quarters in 2004. *See* Ex. 2, ¶ 2.

In 2005, Mrs. Parks came one spot away from winning Sales Representative of the Year for the second year in a row, and she ranked second nationally in 2005 among Alpharma sales

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and Faulding Laboratories no longer exist, and Alpharma divested Purepac Pharmaceutical Co. in 2005.

representatives. She was a member of the Circle of Excellence for 2005 and she was the Representative of the Quarter for the Second Quarter in 2005. *See* Ex. 2, ¶ 3.

In February 2006, approximately five months before Alpharma terminated Mrs. Parks' employment, Mrs. Parks earned the Alpharma "High Five" award, which recognizes those sales representatives who best exemplify Alpharma's five "core values": (1) "bias for action," (2) "creativity," (3) "courage," (4) "integrity," and (5) "teamwork." *See* Ex. 2, ¶ 4.

1. Alpharma's Relationship with Michael S. Kaplan, M.D., Ph.D.

a. Kaplan Clinical "Switch" Study

In approximately August 2004, Alpharma entered into a clinical study agreement with a physician from Catonsville, Maryland, Michael S. Kaplan, M.D., Ph.D. (the "**Switch Study**").[2] The primary objective of the study was to assess the efficacy of switching patients from competitor sustained release opiates to Kadian. Exhibit 4 (Deposition of Eric Vandal), p. 44; Exhibit 5 (Deposition of Stephen Sun, M.D.), p. 79; Sun's Dep. Ex. 4 (Switch Study agreement). The secondary objective of the study was to "assess the pharmacoeconomic impact of switching from other sustained release opiates to Kadian," which means to assess the cost effectiveness, safety, and efficiency of treating patients with Kadian compared to other sustained release opiates, including assessing whether the patients pay less money for their pain prescriptions and physicians spend less time treating the patient. *See* Sun's Dep. Ex. 4, at P000466; Ex. 2 (Parks Aff.), ¶ 5. Alpharma budgeted $50,000 to pay Dr. Kaplan for study and the entire study was to last over a three month time period. *See* Ex. 5 (Sun Depo.), pp. 95, 77. Stephen Sun, M.D., Alpharma's Director of Clinical Research and Medical Affairs, explained the Switch Study was a

[2] Dr. Kaplan was an adjunct faculty member at Johns Hopkins School of Medicine. *See* Exhibit 3 (Deposition of Joseph Stauffer, D.O.), p. 123.

"Phase IV" study, which meant Alpharma had to report information about the study to the United States Food and Drug Administration ("FDA"), including any "adverse events" involving patients, as part of an annual report. Alpharma then would publish the study to contribute to "medical science." *See id.* at pp. 74-75.

i. Formulary Committees

During Mrs. Parks's employment at Alpharma, Alpharma actively sought to have Kadian added to Medicare, Medicaid and Federal and State-funded health care program formularies. Formularies are lists of drugs that are covered by a given health plan. In seeking to persuade Medicaid and other Government-related formulary committees to add Kadian to their formularies, Alpharma would supply the committees with clinical studies in an attempt to prove Kadian's effectiveness. *See* Ex. 2 (Parks Aff.), ¶ 6.

ii. Background on Dr. Kaplan

Before Mrs. Parks started working at Alpharma, Dr. Kaplan had spent a lot of time working with the Alpharma marketing team on what was known as the "KRONUS" study. Dr. Kaplan had been promised that he would be the chief clinical investigator and that he would be on the Alpharma advisory board for the KRONUS study, but Alpharma eventually decided not to ask Dr. Kaplan to be the chief clinical investigator or to be on the advisory board. Instead he was invited to be a mere participant in the KRONUS study, which upset Dr. Kaplan. In response, Dr. Kaplan stopped writing new Kadian prescriptions. *See* Ex. 1 (Parks Depo.), pp. 63-64; Ex. 2 (Parks Aff.), ¶ 7.

After Mrs. Parks started at Alpharma, however, she sought to win Dr. Kaplan's business back, since he was a physician in Mrs. Parks's sales territory. Mrs. Parks spent several months making sales calls on Dr. Kaplan and she discovered that Dr. Kaplan liked Kadian and he

thought it was an effective drug. *See* Ex. 1 (Parks Depo.), p. 64-65. Dr. Kaplan's Kadian prescriptions eventually started increasing and Alpharma offered Dr. Kaplan a study with a $10,000 payment and started inviting Dr. Kaplan to Advisory Board Meetings.[3] The objective of that $10,000 study was to perform a retrospective "chart pull" showing that Kadian was cheaper and more efficacious than its competitors. Dr. Kaplan was to present the results of the "chart pull" study through an abstract at the American Pain Society meeting in Vancouver, Canada in mid-2004. Mike A. Royal, M.D. took over as the Medical Director of Alpharma around that time, however, and after he received Dr. Kaplan's abstract for the Vancouver meeting, he cancelled the Vancouver trip because Dr. Royal believed Dr. Kaplan had failed to support the abstract with sufficient data. *See* Ex. 2 (Parks Aff.), ¶ 8; Exhibit 6 (Royal 4/29/04 email).

Dr. Kaplan and his wife, Marjie Kaplan ("Mrs. Kaplan"), who planned to attend the Vancouver meeting with Dr. Kaplan, became upset after Alpharma suddenly cancelled their trip. Dr. Kaplan felt Alpharma had reneged on the "chart pull" study. As a result, Ron Rocca, the Director of Sales at Alpharma, and Dr. Royal offered the Switch Study to Dr. Kaplan as an "apology" for the Vancouver meeting fall-out. *See* Ex. 1 (Parks Depo.), p. 486, 518; Ex. 7 (LaFay Depo.), p. 287. The decision to enter into the Switch Study with Dr. Kaplan was made

[3] Advisory boards were a method of funneling illegal kickbacks to physicians. Alpharma would pay physicians $1,500 or more and provide all-expense paid trips to fancy resorts and the physicians would not do any substantial work in return. *See* Ex. 1 (Parks Depo.), p. 476. As Alpharma's Director of Sales, Craig LaFay, testified, "[a]n Ad board is something where doctors would go and give advice to the company about their products" and they would get paid in return. Exhibit 7 (Deposition of Craig LaFay), p. 57. Mr. LaFay testified the point of inviting the doctors to the Ad Board meetings was that "you would like to see them write more" Kadian prescriptions. *Id*. at 94-95. The Ad Board meetings took place at "nice places"; for example, one took place at the Inn at Spanish Bay in Pebble Beach, California, and the physicians had all of their expenses paid for and they received payment for their time as part of the advisory board. *Id.* at 95-97.

by senior management at Alpharma and Mrs. Parks had no role in that decision-making, nor did she have any knowledge that Ron Rocca and Dr. Royal had decided to offer the Switch Study to Dr. Kaplan. Rather, that decision was made and communicated to Dr. Kaplan and then conveyed to Mrs. Parks. *See* Ex. 1 (Parks Depo.), p. 480; Exhibit 8 (Royal 5/13/04 email); Ex. 2 (Parks Aff.), ¶ 9. [4]

Later in July 2004, Mrs. Kaplan started complaining to Mrs. Parks that Dr. Royal was not returning Dr. Kaplan's phone calls regarding the Switch Study and Mrs. Parks forwarded Mrs. Kaplan's complaints to her supervisors at Alpharma. Joseph Stauffer, D.O., who Alpharma had hired in June 2004 as the Vice President of Global Medical Affairs, received a telephone call from Ron Rocca around this time about setting up a dinner meeting between Dr. Stauffer, Dr. Kaplan and Mrs. Parks at the Charleston Restaurant in downtown Baltimore. The dinner meeting took place on August 6, 2004 and the Switch Study is the study that grew out of the dinner meeting between Dr. Stauffer, Dr. Kaplan, and Mrs. Parks. Ex. 3 (Stauffer Depo.), pp. 31-34, 42; Ex. 2 (Parks Aff.), ¶ 10.

After the August dinner meeting, on August 11, 2004, Michael Slesinski, the Regional Sales Director for Alpharma's East Region, asked for assistance from Ron Rocca in expediting finalization of the agreement with Dr. Kaplan for the Switch Study:

> I guess what I'm asking for Ron is your help and support in getting this situation resolved quickly. *I know that Kaplan can be a pain in the ass and is looking for a payout, but the fact is he is the biggest Kadian supporter we have and quite frankly we can't afford to loose (sic) his business*.

[4] While others at Alpharma felt they had to give Dr. Kaplan the Switch Study to keep Dr. Kaplan's Kadian prescriptions up, Mrs. Parks felt she was capable of continuing Dr. Kaplan's business without the Switch Study. *See* Ex. 1 (Parks Depo.), p. 518.

Exhibit 9 (Slesinski 8/11/04 email); Ex. 2 (Parks Aff.), ¶ 11. In reply, Ron Rocca wrote back: "I spoke to Joe [Stauffer]. And he is going to do everything possible to get the study going." *Id.* After that exchange of emails, Dr. Royal put Mrs. Parks in charge of handling the Switch Study. In an email dated August 13, 2004, Dr. Royal wrote to Mrs. Parks:

> Our goal is to meet the early 2005 abstract deadlines for spring meetings. Your job again is to help him [Dr. Kaplan] meet those deadlines. That is the only way he will receive additional moneys. On a happier note, congrats again for the super job. You have to be a saint to put up with the likes of MK [Dr. Kaplan] on a regular basis.

Exhibit 10 (Royal 8/13/04 email); Ex. 2 (Parks Aff.), ¶ 12.

iii. Alpharma Starts the Switch Study

Alpharma paid Dr. Kaplan an initial amount of $26,000 before he started the Switch Study.[5] *See* Exhibit 11 (Royal 8/30/04 email) ("The $26K check is in process with finance."); Ex. 2 (Parks Aff.), ¶ 13. Alpharma's Medical Director of the Switch Study, Stephen Sun, M.D., kept in close contact with Dr. Stauffer concerning the Switch Study and it was Dr. Sun's job to "make [the] study happen." Ex. 7 (Sun Depo.), pp. 68-69.

Dr. Sun visited Dr. Kaplan's office in April 2005 along with Jan Bonalsky, Ph.D., "Alpharma's statistical consultant," to work with Dr. Kaplan on the Switch Study. *See* Exhibit 12 (Sun 3/30/05 email); Ex. 2 (Parks Aff.), ¶ 14. Dr. Bonalsky was the President of De Novo Solutions, who Alpharma had hired to assist with data analysis in the Switch Study. *See* Ex. 7 (Sun Depo.), p. 123; Ex. 6 (Vandal Depo.), p. 54. Mrs. Parks recalls stopping in at Dr. Kaplan's

[5] Dr. Kaplan, Mrs. Kaplan, and their daughter, were all paid as part of the Switch Study. *See* Ex. 5 (Sun Depo.), pp. 93-94.

office in April 2005 and she saw Dr. Bonalsky performing statistical analysis regarding the Switch Study. *See* Ex. 2 (Parks Aff.), ¶ 15.

As the Switch Study neared completion, in October 2005, a dispute arose between the Kaplans and Alpharma concerning final payment for the Switch Study. Mrs. Parks started receiving complaints from the Kaplans, including complaints that executives at Alpharma were not calling Dr. Kaplan back. *See* Exhibit 13 (Parks 10/5/05 email); Exhibit 14 (Parks10/12/05 email). Also, Dr. Sun had been scheduled to meet the Kaplans and Angie Milliman, N.P. for dinner in Baltimore to celebrate the end of the Switch Study and to give the Kaplans their final payment for the study. But shortly before that dinner, Dr. Sun cancelled and Mrs. Parks had to fill-in for Dr. Sun at the dinner and the Kaplans were insulted that Dr. Sun cancelled. *See* Ex. 2 (Parks Aff.), ¶ 16.[6]

On October 25, 2005, a representative from Medical Action Communications ("MAC"), Linda Cooney, contacted Dr. Kaplan concerning the abstract for Dr. Kaplan's Switch Study. Alpharma hired MAC to write the abstract on the Switch Study for Dr. Kaplan and Ms. Cooney forwarded drafts of the abstract to Dr. Kaplan on October 25, 2005, which Ms. Cooney planned to submit to the American Pain Society ("APS") and American Academy of Pain Medicine ("AAPM") for upcoming conferences. *See* Ex. 4 (Vandal Depo.), pp. 48-49; Ex. 5 (Sun Depo.), p. 90; Exhibit 15 (Kaplan 10/25/05 email); Ex. 2 (Parks Aff.), ¶ 17. Ms. Cooney gave Dr. Kaplan three days to get back to her regarding the abstract before it had to be submitted to APS

[6] Dr. Sun testified that he was "remotely aware" that Ms. Parks discussed with him the fact that Dr. Ron Warner and Dr. Joe Stauffer were not calling Dr. Kaplan back and that Dr. Kaplan was upset about that. *See* Ex. 5 (Sun Depo.), p. 179.

and AAPM, but Dr. Kaplan refused to sign off on the final abstract until Alpharma paid him the remaining amount of money for the Switch Study. *See* Ex. 2 (Parks Aff.), ¶ 17.

iv. Dr. Kaplan's Switch Study Showed Kadian Had A Negative Pharmacoeconomic Impact

The dispute between the Kaplans and Alpharma over the Switch Study in October 2005 prompted Mrs. Parks to contact Dr. Sun in approximately late October 2005. During a telephone call with Dr. Sun, Dr. Sun told Mrs. Parks that Dr. Kaplan's Switch Study was a "failure" because (1) Dr. Kaplan had patients who were on very high doses of morphine, and considering the regulatory environment at the time, Alpharma did not want Kadian to be associated with high-dose patients; and (2) the study revealed that switching patients to Kadian required that patients be placed on 30%-50% **higher doses** of morphine, meaning switching patients to Kadian had a **negative** pharmacoeconomic impact (i.e. switching patients to Kadian cost more money). As a result, Dr. Sun stated Alpharma did not want the results of the study to be released. Mrs. Parks objected that Alpharma had decided to disassociate itself from high-dose morphine patients, but Dr. Sun replied "that's the way it is." Dr. Sun told Mrs. Parks that Alpharma was not concerned with whether Dr. Kaplan submitted his abstract to APS or APPM. *See* Ex. 2 (Parks Aff.), ¶ 18.

Linda Cooney eventually submitted the abstract on Dr. Kaplan's Switch Study to the AAPM and APS. *See* Ex. 5 (Sun Depo.), p. 137. The abstract poster MAC prepared on behalf of Dr. Kaplan did not disclose that switching patients to Kadian proved to have a negative pharmacoeconomic effect, even though assessing the pharmacoeconomic impact of switching from other sustained release opiates to Kadian had been an objective of the Switch Study. *See*

Ex. 3 (Stauffer Depo.), pp. 43-44, 52, 54; Ex. 5 (Sun Depo.), pp. 112-113. [7] Dr. Sun testified that modifying an endpoint of a pharmaceutical study would be "ludicrous," and a pharmaceutical company cannot change the endpoints of a study once the study has been completed. *See* Ex. 5 (Sun Depo.), pp. 75-76. But that is precisely what Alpharma did with respect to the pharmacoeconomic results of the Switch Study. [8] *See* Ex. 5 (Sun Depo.), pp. 112-113.

v. Mrs. Parks Objected When Alpharma Buried the Results of the Switch Study

On December 14, 2005, Mrs. Parks met with Craig LaFay in person at Alpharma's headquarters in Piscataway, New Jersey. Mrs. Parks told Mr. LaFay she was very unhappy that Alpharma had decided to "bury" the pharmacoeconomic results of the Switch Study and that Dr. Kaplan had performed the study in good faith. Mrs. Parks spoke to Mike Slesinski on the telephone on December 15, 2005 and stated she did not like that Alpharma had decided to bury the pharmacoeconomic results of the Switch Study. *See* Ex. 2 (Parks Aff.), ¶ 19. Mrs. Parks also complained to Mr. Slesinski that MAC had "ghost written" the study abstract for Dr. Kaplan. *See* Ex. 1 (Parks Depo.), p. 170.

In late-December 2005, Alpharma learned that the APS had approved Dr. Kaplan's Switch Study abstract and invited Dr. Kaplan to come and present the abstract poster at a

[7] Dr. Sun testified the results of the Switch Study showed that switching patients to Kadian, at month one, required increasing the patients' morphine dose from baseline by **21%**; at month two, by **23%**; and at month three, by **27%**. *See* Ex. 5 (Sun Depo.), p. 116; Sun's Dep. Ex. 9-E.

[8] Alpharma had discussed with Dr. Kaplan the possibility of extending Dr. Kaplan's Switch Study and replicating the study in doctor's offices across the country, but that never happened. *See* Ex. 3 (Stauffer Depo.), p. 59.

conference in San Antonio, Texas in early May 2006. *See* Ex. 4 (Vandal Depo.), p. 83; Exhibit 16 (Vandal 12/22/05 email). No one at Alpharma expected APS to accept Dr. Kaplan's poster abstract and the news came as a surprise. *See* Ex. 2 (Parks Aff.), ¶ 20.

On April 18, 2006, Angie Milliman, N.P., a nurse practitioner in Dr. Kaplan's office who was a co-author of the Switch Study abstract, forwarded Mrs. Parks the finalized abstract poster that MAC had prepared for Dr. Kaplan to present at the APS meeting. *See* Exhibit 17 (Milliman 4/18/06 email). That abstract poster did not provide any information concerning the negative pharmacoeconomic results of the Switch Study. *Id.*; Ex. 3 (Stauffer Depo.), pp. 52, 54. Mrs. Parks later discussed with Kirk DuMont and Mike Slesinski whether Alpharma would produce a second abstract disclosing the pharmacoeconomic results of the Switch Study, and Mr. DuMont and Mr. Slesinski assured Mrs. Parks that MAC would produce such an abstract. But MAC never did. After Angie Milliman, N.P. presented the Switch Study poster abstract at the APS meeting in May 2006, Mrs. Parks forwarded a copy of the abstract poster to her supervisor, Kirk DuMont, on June 10, 2006, explaining that the poster had already been presented. Mrs. Parks sent the email to prove to Mr. DuMont that MAC never prepared a second poster abstract for Dr. Kaplan that disclosed the pharmacoeconomic results of the Switch Study. *See* Ex. 2 (Parks Aff.), ¶ 21; Exhibit 18 (Parks 6/10/06 email).

Suppressing the pharmacoeconomic results of the Switch Study ultimately enabled Alpharma to continue to represent to Medicaid and other Government-related formulary committees that Kadian was cost-effective and safe so that Kadian would be added to their formularies. *See* Ex. 2 (Parks Aff.), ¶ 22.

b. "Kaplan Method" of Converting Patients to Kadian

On June 16, 2005, Mike Slesinski emailed Mrs. Parks about setting up a dinner meeting between himself, Craig LaFay, Pete Hill, Mrs. Parks and Dr. Kaplan in Baltimore during the last two weeks of July 2005. Mr. Slesinski explained the purpose of the dinner meeting would be two-fold: "[w]e would like to thank him [Dr. Kaplan] for his contribution in the study he participated in and to see if he would be interested in speaking at our Regional Meeting in Atlanta on August 25th [2005]." *See* Exhibit 19 (Slesinski 6/16/05 email); Ex. 2 (Parks Aff.), ¶ 23; Ex. 7 (LaFay Depo.), p. 253. After that dinner with Dr. Kaplan, Mrs. Parks was asked to prepare a slide presentation for Dr. Kaplan to present at the Atlanta regional meeting. *See* Ex. 7 (LaFay Depo.), p. 258.

On August 25, 2005, Dr. Kaplan gave a presentation entitled "Year of the Switch" to Alpharma sales representatives in Atlanta at the Alpharma Regional Meeting.[9] One of the slides in Dr. Kaplan's Atlanta presentation instructed:

> Instead of switching the patient over completely to Kadian, the doctor may *add* Kadian to the current short-acting regimen.
>
> The patient will most likely be dosed an IR for breakthrough pain anyway. Once Kadian reaches steady state plasma levels, the patient usually begins to wean themselves off the IR.

[9] On August 9, 2005, Dr. Sun emailed Mrs. Parks a slide presentation he had prepared for Alpharma's national meeting entitled "Year of the Switch," and many of the slides were later used in Dr. Kaplan's Atlanta presentation. *See* Exhibit 20 (Sun 8/9/05 email with "Year of the Switch" Presentation). Mrs. Parks communicated back and forth with Kandi Marlowe, Alpharma's East Region Field Training Manager, and George Wagner, Alpharma's Director of Regulatory Affairs, concerning the Atlanta slide presentation and Mr. Wagner ultimately approved the slide presentation. Exhibit 21 (Wagner 8/18/05 email); Ex. 2 (Parks Aff.), ¶ 24.

> This is an easier conversion method than taking away the patient's IR dosing completely.

Exhibit 22 (Kaplan Atlanta Presentation, p. 23) (emphasis added). With this slide, Dr. Kaplan explained that patients could self-dose their short-acting[10] pain medications (e.g. Oxycontin, Percocet), and Kadian could be prescribed simultaneously. *See* Ex. 2 (Parks Aff.), ¶ 24; Ex. 1 (Parks Depo.), pp. 417-418.

At the time of the Atlanta presentation, Dr. Kaplan described the conversion method as his "personal conversion method," but Alpharma hired Dr. Kaplan to speak at the meeting for the purpose of **training** sales representatives on how to instruct their physicians who were resistant to switching their patients to Kadian about an effective conversion method. Dr. Kaplan's conversion method became known within Alpharma as the "Kaplan Method." *See* Ex. 2 (Parks Aff.), ¶ 25.

i. Mrs. Parks Complained About the Kaplan Conversion Method

Almost immediately after Dr. Kaplan's Atlanta presentation, Mrs. Parks started receiving telephone calls from sales representatives who had questions about Dr. Kaplan's conversion method. Mrs. Parks became overwhelmed with the number of calls she received, so on August 31, 2005, she suggested to Mike Slesinski and Peter Hill that Alpharma organize a group conference call to "walk through the conversion" method for the representatives and to answer questions. Ex. 1 (Parks Depo.), pp. 471-472; Parks Depo. Exhibit 55 (Parks 8/31/05 email). Mrs. Parks sent the email to Mr. Slesinski and Mr. Hill because she was concerned that no one

[10] "Short-acting" pain medications are medications that do not have a sustained release mechanism like Kadian (e.g. Oxycontin or Percocet), and they provide immediate pain relief that gradually wears off.

understood the conversion method and she wanted to review "the knowledge gap . . . to be able to ensure the [representatives] . . . [understood] the conversion because it was a serious matter and could endanger patient's safety." Ex. 1 (Parks Depo.), p. 496. Mr. Slesinski forwarded Mrs. Parks's suggestion for a conference call to Craig LaFay and Kandi Marlowe on September 1, 2005, but Mr. LaFay refused to allow the company-wide conference call. *See* Parks Depo. Ex. 55; Ex. 2 (Parks Aff.), ¶ 26.

Mrs. Parks then started to complain to her superiors at Alpharma that the Kaplan conversion method was an "off-label" promotion of Kadian and that Alpharma's sales representatives did not understand the conversion method when describing it to physicians in the field.[11] Specifically, Mrs. Parks spoke to Craig LaFay in person at Alpharma's headquarters in Piscataway, New Jersey in November 2005 and stated she did not want to be part of a sales training group that promoted Dr. Kaplan's conversion method when the sales representatives did not understand the conversion method. Mrs. Parks also complained to her manager, Pete Hill, during field rides that sales representatives did not understand the Kaplan conversion method.[12] Mrs. Parks also complained to Mike Slesinski several times over the telephone that sales representatives were simplifying the Kaplan conversion method because they did not fully

[11] "Off-label" marketing is promoting a drug for use in treating conditions other than the conditions specific in the drug's FDA-approved labeling, or treating the approved conditions in an unapproved manner (e.g., with a higher dose than is approved). Federal law and regulations prohibit drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. *See* 21 U.S.C. §§ 331(a), (d), 352(a), 355(a), (b), (d); 21 C.F.R. § 201.57(c)(2)(iv); *see generally Wash. Legal Found. v. Henney*, 202 F. 3d 331, 332-333 (2000) (outlining statutory and regulatory scheme).

[12] Mr. Hill would direct other sales representatives who had questions about the Kaplan conversion method to Mrs. Parks. *See* Ex. 2 (Parks Aff.) , ¶ 27.

understand it, and thus were promoting an off-label conversion method. *See* Ex. 2 (Parks Aff.), ¶ 27.

At deposition, Mrs. Parks testified that when she complained to her superiors at Alpharma about the Kaplan conversion method, she said it was "**off-label which is the same—which is illegal in the pharmaceutical or it's, you know, fraudulent**. . . ." Ex. 1 (Parks Depo.), p. 474 (emphasis added). She further answered: "**I said it was off-label which in the pharmaceutical industry is fraudulent to market an off-label use**." *Id.* (emphasis added).

c. Dr. Kaplan's Coventry Presentation in February 2006

In approximately December 2005, Dr. Sun sent a letter to Dr. Kaplan requesting that Dr. Kaplan participate in training to speak on behalf of Alpharma. *See* Exhibit 23 (Sun letter to Kaplan); Ex. 2 (Parks Aff.), ¶ 28. After receiving the letter from Dr. Sun, Dr. Kaplan was insulted that Alpharma had asked him to be a "mere participant" in speaker training considering he "spoke at [Alpharma's] Atlanta meeting to train [sales representatives] on Kadian" and Dr. Kaplan felt he should be leading the speaker training. Dr. Kaplan threw out the letter from Dr. Sun and the materials for speaker training and refused to participate. Mrs. Parks notified both Pete Hill and Craig LaFay that Dr. Kaplan was upset about having to participate in speaker training. *See* Exhibit 24 (Parks 1/3/06 email); Ex. 2 (Parks Aff.), ¶ 28. The purpose of Alpharma's speaker training program in January 2006 was to ensure the physician speakers promoted Kadian according to its label and to prevent the "off-label" promotion of Kadian. *See* Ex. 2 (Parks Aff.), ¶ 28.[13]

[13] Mrs. Parks and her manager at the time, Pete Hill, both had to sign a "conduct statement" in the beginning of January 2006 agreeing that they would not submit any check request on behalf of

i. Mrs. Parks Objected When Alpharma Proposed that Dr. Kaplan Give An Off-Label Presentation to Coventry Healthcare

Craig LaFay and Dr. Stauffer both testified that Kadian is not less prone to abuse and diversion compared to other pain medications on the market, and therefore, promoting Kadian as less prone to abuse and diversion is an off-label marketing tactic. *See* Ex. 7 (LaFay Depo.), p. 122; Ex. 3 (Stauffer Depo.), p. 28.

On February 2, 2006, Matt Anderson, Alpharma's Managed Care representative at Alpharma, contacted Debra Parks about having Dr. Kaplan give a telephone conference presentation to Coventry Healthcare on February 6, 2006 at 2 p.m. *See* Ex. 1 (Parks Depo.), p. 165; Exhibit 25 (Anderson 2/2/06 email); Ex. 2 (Parks Aff.), ¶ 29. After Mrs. Parks spoke to Matt Anderson about the proposed presentation, Mrs. Parks immediately contacted Pete Hill and Mike Slesinski informing them that Mr. Anderson wanted Dr. Kaplan to promote Kadian as less prone to abuse and diversion compared to other pain medications and that she objected to such a presentation:

> FYI: Matt Anderson called me Thursday evening to help him with his teleconference this Monday with the clinical team from Coventry Health . . . . Matt said that MM's tactic was to sell Kadian on the "less diversion potential therefore the plan saves money because they are not paying for the drug to be sold on the street." ***Between us, I am not at all comfortable with this approach. If it were me[,] I would not do this.*** The success with Medicaid in MD was due to strong ***clinical support*** from my docs and a great detail by Dr. Royal 1 1/2 yrs. ago using KRONUS data. Mike- did you know that this is their pitch?

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any health care provider, unless that health care provider had been approved as a speaker and had participated in speaker training. *See* Ex. 1 (Parks Depo.), pp. 128-129.

Exhibit 26 (Parks 2/4/06 email) (emphasis added); Ex. 2 (Parks Aff.), ¶ 29. In addition to objecting to the proposed off-label message, Mrs. Parks also objected to Mike Slesinski that Dr. Kaplan was not an approved speaker as of February 2006. *See* Ex. 1 (Parks Depo.), p. 131.

On February 6, 2006, Mr. Anderson forwarded Mrs. Parks a PowerPoint slide presentation that he had created that had as one of the introductory slides Rush Limbaugh on the cover of Newsweek, with the headline: "Rush's World of Pain: His Path to Pill Addiction." The same slide had another Newsweek cover that stated: "Painkillers: Vicodin and OxyContin: Hot Drugs That Offer Relief—and Danger." *See* Exhibit 27 (Limbaugh Slide Presentation); Ex. 2 (Parks Aff.) , ¶ 30. Mr. Anderson's obvious point just from that one slide with Rush Limbaugh on the cover of Newsweek was to convey that Kadian was less prone to abuse and diversion compared to other opioids, such as OxyContin and Vicodin. *See* Ex. 2, ¶ 30. Again, Mrs. Parks immediately objected to the off-label message in Mr. Anderson's proposed presentation and she forwarded the slide presentation to Mr. Slesinski and in the email wrote:

> this is for your eyes only. The main issues we have been having with Coventry are BID [twice a day] reimbursement[.] If it were me, I would have the Royal slide, a BID plasma graph, etc- ***clinical info.*** But I am not a MM rep so perhaps I am off-base. This teleconference is for the whole clinical team.

Exhibit 28 (Parks 2/6/06 email) (emphasis added); Ex. 2, ¶ 30; Ex. 1 (Parks Depo.), p. 134.

Because of Mrs. Parks's objections, Dr. Kaplan never used the Rush Limbaugh slide presentation proposed by Mr. Anderson when he spoke to Coventry on February 6, 2006. The next issue, however, after Dr. Kaplan spoke to Coventry, was how Alpharma would pay Dr. Kaplan for his services since he was not an approved speaker. Alpharma had agreed to pay Dr. Kaplan a $500 honorarium for giving the ten minute telephone presentation. *See* Ex. 2 (Parks

Aff.) , ¶ 31. [14] After the Coventry presentation in February 2006, Mrs. Parks received telephone calls from Mr. Hill and Mr. LaFay who told her that processing Dr. Kaplan's payment was going to be a "big problem" because Dr. Kaplan was not an approved speaker. *See* Ex. 1 (Parks Depo.), pp. 130-131; Exhibit 29 (Anderson 2/9/06 email to Mrs. Parks: "I spoke to Pete [Hill] and Craig [LaFay] about how to compensate Kaplan for his services."); Ex. 2 (Parks Aff.) , ¶ 31.

Weeks went by and Alpharma never paid Dr. Kaplan for his services. Eventually, Mr. Hill instructed Mrs. Parks to pay Dr. Kaplan a $500 gift certificate with her Alpharma American Express card, but Mrs. Parks refused to do it because she thought it would be improper. *See* Ex. 1 (Parks Depo.), p. 128-130. Craig LaFay, himself, testified at deposition that it would have been inappropriate, pursuant to Alpharma guidelines, for Mr. Hill to have instructed Mrs. Parks to put an honorarium for Dr. Kaplan on her American Express card. *See* Ex. 7 (LaFay Depo.), p. 214. Nevertheless, Mr. Hill told Mrs. Parks repeatedly: "You're going to have to find a way to pay him [Dr. Kaplan] on your own. Just buy him gift certificates and I will approve it." Ex. 1 (Parks Depo.), p. 137. Mr. Hill told Mrs. Parks that he was very upset with her that she refused to pay Dr. Kaplan his honorarium with her American Express card, and he told Mrs. Parks: "You don't trust me . . . You don't trust Craig [LaFay]." *See id.* at p. 137. But Mrs. Parks continued to refuse. *See id.*

Eventually, Dr. Kaplan started calling Ron Warner, the Vice President of Alpharma, to complain that he had not been paid for the Coventry presentation. Craig LaFay then contacted Mrs. Parks to tell her that his secretary, Jeanie Wayman, had just sent by FedEx to Mrs. Parks'

[14] Typically, to pay a speaker, Alpharma required that a W-9 form be submitted to process a check request. Alpharma would then approve the payment, pay the speaker, and issue a Form 1099. *See* Ex. 7 (LaFay Depo.), pp. 194, 205. Alpharma speakers were also supposed to sign a consultant agreement before presenting on behalf of Alpharma. *See* Ex. 4 (Vandal Depo.), p. 77.

home a private agreement that Dr. Kaplan had to sign, and that Mr. LaFay would then be able to facilitate the check request for Dr. Kaplan. *See* Ex. 1 (Parks Depo.), p. 137. But Mrs. Parks refused to deliver the agreement to Dr. Kaplan to sign. Mr. LaFay responded, "Okay. I will have Pete come and do it." Mrs. Parks received that FedEx envelope from Mr. LaFay, but she never opened it and just gave it to Mr. Hill the next morning during their field ride together. Mr. Hill later handled the execution of the agreement with Dr. Kaplan and Alpharma eventually paid Dr. Kaplan. *Id.* at p. 138.

2. Clinical Studies into Risks of "Dose-Dumping" When Kadian Is Consumed with Alcohol

In approximately July 2005, the FDA asked Purdue Pharma to withdraw Palladone, a sustained release pain medication similar to Kadian, from the market because of risks of "dose-dumping" – the sudden release of the full strength of Palladone – when consumed with alcohol. *See* Exhibit 30 (Parks 7/14/05 email); Ex. 2 (Parks Aff.) , ¶ 32; Exhibit 31 (Washington Post Article, 7/14/05, "Painkiller Palladone Pulled Over Alcohol Risk"). Dr. Stauffer explained that after Purdue Pharma pulled Palladone off the market, the FDA became concerned with whether Kadian had a similar dose-dumping effect with alcohol. Dr. Stauffer testified Purdue Pharma pulling Palladone off the market "opened up Pandora's box for the FDA" and the FDA went to every pharmaceutical company that manufactured long-acting opioids and requested that they perform trials to test for possible dose-dumping with alcohol. Dr. Stauffer explained the alternative to doing clinical trials was to place a "black box warning" on Kadian's package insert, but Alpharma decided to perform clinical trials instead. *See* Ex. 3 (Stauffer Depo.), p. 93-94; *see* Ex. 5 (Sun Depo.), pp. 184-185; Ex. 4 (Vandal Depo.), p. 84. Alpharma could not "tout or promote" Kadian on the basis that it was safe when taken with alcohol until *after* Alpharma

completed its clinical trials to determine whether Kadian dose-dumped with alcohol and confirmed there was no risk of dose-dumping. *See* Ex. 3 (Stauffer Depo.), p. 95.

In approximately July 2005, Mrs. Parks learned from Angie Milliman, N.P., who worked in Dr. Kaplan's office, that one of Ms. Milliman's patients had died from dose-dumping after her patient had consumed both Oxycontin and alcohol on July 4, 2005. *See* Ex. 2 (Parks Aff.) , ¶ 33. In October 2005, Ligand Pharmaceuticals, Inc., a competitor of Alpharma's, issued a "Dear Doctor" letter informing health care professionals that it was adding a black box label warning to the label of Avinza, a sustained release morphine sulfate capsule.[15] *See* Exhibit 32 (Ligand Dear Doctor Letter; P002223); Ex. 2 (Parks Aff.) , ¶ 33. Alpharma's Director of Sales Operations for Alpharma at the time, Craig LaFay, testified that after Ligand discovered that Avinza had a dose-dumping effect when taken with alcohol, Alpharma started marketing Kadian on the basis that Kadian could be taken with alcohol without any adverse effect. *See* Ex. 7 (LaFay Depo.), pp. 235-236, 244.

a. Alpharma's Clinical Trials Regarding Dose-Dumping with Alcohol

In approximately November 2005, Dr. George Wagner and Dr. Stauffer requested that Mrs. Parks obtain a copy of the clinical trial protocol that Purdue Pharma had used in its alcohol clinical trials concerning Palladone. Mrs. Parks indicated that she could obtain a monograph for the Purdue Pharma clinical trial because she knew a physician who had been involved with the Purdue Pharma clinical trials. *See* Ex. 1 (Parks Depo.), p. 426. On approximately November 18,

[15] Avinza's black box label warning stated that "Patients must not consume alcoholic beverages while on AVINZA therapy. . . . Consumption of alcohol while taking AVINZA may result in the rapid release and absorption of a potentially fatal dose of morphine." *See* Ex. 32 (Ligand "Dear Doctor" Letter).

2005, Mrs. Parks went to Alpharma's headquarters in Piscataway, New Jersey to interview for a training position. She gave Dr. Wagner and Dr. Stauffer the Purdue Pharma clinical trial monograph during that visit. After reviewing the monograph that day, Dr. Wagner and Dr. Stauffer thanked Mrs. Parks in person for obtaining it and they told Mrs. Parks they would use Purdue Pharma's clinical trial protocol in researching whether Kadian showed any adverse effect when taken with alcohol. *See* Ex. 2 (Parks Aff.) , ¶ 34.

Alpharma performed two different types of study in determining whether Kadian dose-dumped when consumed with alcohol: an "in vitro" study, which means a study performed with test-tubes only; and an "in vivo" study, which means a study performed with human patients. Alpharma performed the in vitro study first, which revealed that Kadian had a "complete drug release once it was placed in a buffer solution containing alcohol." *See* Exhibit 33 (FDA November 2008 Alcohol Study report, see p. 2 of "AC Background"); Exhibit 34 (Affidavit of Robert C. Morgan, Esq.); *see also* Ex. 4 (Vandal Depo.), p. 91. After the in vitro study, Alpharma went on to conduct in vivo testing with alcohol. *See* Ex. 5 (Sun Depo.), p. 193. The results of the in vivo study ultimately showed that Kadian did not dose dump; however, Alpharma did not obtain the final results of the in vivo study until **February 27, 2007**, at the earliest. *See* Ex. 3 (Stauffer Depo.), pp. 98-99. From October 2005 through and until at least the time of Mrs. Parks's termination in July 2006, Alpharma instructed its sales representatives to market Kadian as safe with alcohol, even though Alpharma had no scientific data to support that assertion. *See* Ex. 2 (Parks Aff.), ¶ 35; Ex. 1 (Parks Depo.), pp. 421, 428-429.

In approximately February 2006, Mrs. Parks spoke to a sales representative from Xanodyne Pharmaceuticals, Inc., George Bhailey, and Mr. Bhailey told Mrs. Parks that

Alpharma was considering purchasing Oramorph, a competitor drug of Kadian manufactured by Xanodyne, because Alpharma was concerned the clinical trials would show risks of dose dumping in Kadian when consumed with alcohol. [16] Mrs. Parks reported what Mr. Bhailey had told her to Peter Hill and Mike Slesinski, who both denied that Kadian dose-dumped when consumed with alcohol. Mrs. Parks also reported it to Eric Vandal, who also denied that Kadian had any issue with dose-dumping. *See* Ex. 2 (Parks Aff.), ¶ 36.[17]

b. Mrs. Parks Objects to Alpharma's Marketing of Kadian as Safe With Alcohol After She Learns Clinical Trials Showed Kadian Dose-Dumped With Alcohol

On approximately February 9, 2006, Mrs. Parks had dinner with James Meade, another Alpharma sales representative, at Phillips Restaurant in downtown Baltimore after the two had spent the day together at a meeting with Maryland State Medicaid. During that dinner, Mr. Meade told Mrs. Parks that he had been at Alpharma's headquarters and Dr. Sun told Mr. Meade that the alcohol clinical trials with Kadian had a dose-dumping effect starting at 92 mg of Kadian. Mr. Meade stated that in preparation of the FDA finding out, Alpharma was filing a new drug application for an 80 mg capsule of Kadian, that the 100 mg capsule would be pulled from the market, and that the 200 mg capsule that Alpharma had planned to unveil would never be released. Mrs. Parks told Mr. Meade she was very concerned that Alpharma seemed to be manipulating the results of the alcohol clinical testing, rather than disclosing the results to the FDA. Mr. Meade's statements prompted Mrs. Parks to call Dr. Sun on the telephone soon after

[16] While Alpharma's in vivo study was pending, Alpharma did consider the possibility of purchasing Oramorph from Xanodyne Pharmaceuticals. *See* Ex. 4 (Vandal Depo.), p. 106.

[17] Eric Vandal testified he recalled that Mrs. Parks called him in sometime in the summer of 2006 and "she . . . called expressing concern that a Xanodyne sales representative was claiming that Kadian dose dumped with alcohol, co-ingested with alcohol." Ex. 4 (Vandal Depo.), p. 114.

that dinner. Mrs. Parks repeated to Dr. Sun what Mr. Meade had told her about Kadian dose-dumping when consumed with alcohol. Dr. Sun did not deny Mr. Meade's statement. Rather, Dr. Sun told Mrs. Parks that she should "stop asking questions" and "mind your own business." Ex. 2 (Parks Aff.), ¶ 37; Ex. 1 (Parks Depo.), p. 459.

In approximately late February 2006, Mrs. Parks attended an Alpharma National Sales Meeting in Amelia Island, South Carolina. During a breakfast meeting recognizing Alpharma's "Circle of Excellence" winners for 2005 (including Mrs. Parks), Dr. Stauffer told the Circle of Excellence winners that the participants in the alcohol study were "puking their guts out" because they were "so sick from all the alcohol." Dr. Stauffer joked that "there was no way the study would show any morphine release" because the participants were all "puking." *See* Ex. 2 (Parks Aff.), ¶ 38.[18]

Also during the February 2006 meeting in Amelia Island, Mrs. Parks spoke to Ron Warner, then Vice President of Alpharma, after they ran into each other while walking on the beach. Mrs. Parks told Mr. Warner that Angie Milliman, N.P. told Mrs. Parks that a patient of Ms. Milliman's had died from co-ingesting Oxycontin with alcohol. Mrs. Parks expressed her concerns to Mr. Warner that Alpharma had not reported the results of the clinical trials and that the company appeared to be using the delay before it received the final results as an advantage in marketing that Kadian had no risk of adverse events when co-ingested with alcohol. Mrs. Parks told Mr. Warner that she had heard from George Bhailey that Alpharma was considering buying Oramorph. As to the final results of the alcohol clinical trials, Mrs. Parks asked Mr. Warner:

[18] Dr. Stauffer testified that vomiting during the in vivo clinical trials was a "very, very big issue, it's a problem. And a lot of it – we fixed later on, but a lot of it had to do with how fast the subjects were required by the FDA to drink their alcohol." *See* Ex. 3 (Stauffer Depo.), pp. 85-86.

"We will do the right thing?" Mr. Warner denied having any knowledge that Alpharma was marketing Kadian as having no risk of adverse events when co-ingested with alcohol. *See* Ex. 2 (Parks Aff.), ¶ 39; Ex. 1 (Parks Depo.), p. 419. Mrs. Parks voiced similar concerns to Dr. Stauffer during her employment at Alpharma. Ex. 1 (Parks Depo.), pp. 426.

Around this same time period, Mrs. Parks started discussing the alcohol studies with her manager, Peter Hill, during field rides together. Mrs. Parks complained to Mr. Hill that she "was very worried with the alcohol absorption study that was being conducted at the time." Ex. 1 (Parks Depo.), p. 126. Mr. Hill told Mrs. Parks's physicians during those field rides that Kadian did not have a black box label warning concerning risks of co-ingesting Kadian with alcohol; whereas, competitor drugs of Kadian had black-box label warnings regarding alcohol. Mrs. Parks complained to Mr. Hill that he should not be marketing Kadian as not having any risk of adverse effects when co-ingested with alcohol. *See* Ex. 2 (Parks Aff.), ¶ 40. [19]

3. Alpharma's Internet Surveillance Study on Kadian

During Mrs. Parks's employment at Alpharma, Alpharma performed "internet surveillance" of web sites where people who abused prescription drugs posted messages discussing various prescription drugs of choice (the "internet surveillance study"). Alpharma

[19] Although the final results of the in vivo study, which first became available in February 2007, showed that Kadian had no risk of dose-dumping with alcohol, between March 2005 and September 2006, Alpharma did add language to the Kadian label warning of risks of consuming Kadian with alcohol. The newly added language in the September 2006 label states: **"Patients should be advised that KADIAN® should not be taken with alcohol or other CNS depressants (sleeping medication, tranquilizers) except by orders of the prescribing healthcare provider because dangerous additive effects may occur resulting in serious injury or death."** Ex. 5 (Sun Depo.), pp. 225-237; Sun Depo. Exhibits 64 (March 2005 Kadian label) and 65 (September 2006 Kadian label).

performed an actual study into the number of times Kadian was mentioned on the drug-user websites, compared to other pain medications, and according to that study, there were many more mentions of drugs such as OxyContin and Vicodin, and virtually none, or one or two mentions of Kadian only. *See* Ex. 7 (LaFay Depo.), p. 123, 126-127.

Craig LaFay admitted at deposition that when he was a district sales manager at Alpharma, he would tell his sales representatives (who included Mrs. Parks) that they should promote Kadian to their physicians as less prone to abuse and diversion than other comparable pain medications in the market and he did this at the direction of the marketing team at Alpharma. *See* Ex. 7 (LaFay Depo.), pp. 125-126, 147, 152.

On May 12, 2006, Mrs. Parks received an email from another physician on a pain physician's list serve who complained that Alpharma was promoting the internet surveillance study on Kadian. Mrs. Parks forwarded the email to her supervisor, Jim Mahon. *See* Exhibit 35 (Parks 5/12/06 email); Ex. 2 (Parks Aff.), ¶ 41.

Later, at an Alpharma National Meeting in Orlando, Florida in June 2006, Dr. Stauffer gave a presentation to sales representatives on the internet surveillance study. *See* Exhibit 36 (internet surveillance study presentation). After Dr. Stauffer's presentation, Mrs. Parks spoke to Dr. Stauffer and Mr. LaFay about the May 12, 2006 internet blog that criticized the Alpharma internet surveillance study, and she told Dr. Stauffer and Mr. LaFay she was concerned that Alpharma sales representatives were using the study to market Kadian as being less prone to abuse and diversion, which Mr. LaFay and Dr. Stauffer both knew to be off-label marketing. *See* Ex. 2. (Parks Aff.) , ¶ 42; Ex. 7 (LaFay Depo.), p. 122; Ex. 3 (Stauffer Depo.), p. 28, 83.

4. Pete Hill's Retaliatory Behavior Towards Mrs. Parks and Alpharma's Termination of Mrs. Parks in July 2006

In approximately November 2005, Mrs. Parks's District Sales Manager, Peter Hill, started making derogatory comments to Mrs. Parks about her physical appearance. For example, during a lunch meeting in January 2006, Mr. Hill called Mrs. Parks a "chow hound" because Mrs. Parks had recently gained some weight. Mrs. Parks had also dyed her hair a darker color in an attempt to look younger, but Mr. Hill mocked Mrs. Parks's hair color continuously during the lunch meeting in front of other sales representatives. *See* Ex. 1 (Parks Depo.), p. 109-110.

In January 2006, Mrs. Parks's father-in-law died and Mrs. Parks took a personal day on Wednesday, January 18, 2006, to attend the funeral in New Jersey with her family. Starting at 11:30 a.m. on January 18, Pete Hill started calling Mrs. Parks on her cell phone every half hour to remind her that he and Mrs. Parks were scheduled to take a field ride together on Thursday and Friday of that week. Mr. Hill called Mrs. Parks once in the funeral home and once at the grave site. Mrs. Parks explained to Mr. Hill that it would be difficult for her to leave her family and return to work the next day, but Mr. Hill kept repeating to Mrs. Parks that he was "her manager" and he refused to let her take the day off on January 19. Mrs. Parks returned home that evening to go to work on January 19 expecting Mr. Hill to join her for the field ride, but Mr. Hill informed Mrs. Parks that morning he could not meet her because his travel agency had "screwed up his tickets." *Id.* at pp. 142-143.

On approximately February 15, 2006, Mrs. Parks underwent surgery on her shoulder. After the surgery, she started daily physical therapy. On or about February 21, 2006, Pete Hill became upset when he learned that Mrs. Parks did not want to attend the Alpharma National Sales Meeting in Amelia Island, South Carolina from February 26-March 2, 2006 because of her

shoulder surgery. Mr. Hill then instructed Mrs. Parks to send her **medical records** to Mike Slesinski to get permission to stay home from the meeting.[20] Mr. Hill and Mr. Slesinski then threatened firing Mrs. Parks unless she attended the meeting in Amelia Island, so Mrs. Parks attended the meeting. *See* Ex. 2 (Parks Aff.), ¶ 43.

5. Alpharma Terminates Mrs. Parks In July 2006

Alpharma ultimately terminated Mrs. Parks from her employment on July 24, 2006. On that day, Mrs. Parks drove to a hotel near BWI expecting to meet her District Manager, Kirk DuMont, for a field ride, and she was met at the hotel by Craig LaFay and Regina Donohue, the Director of Human Resources at Alpharma. Ms. Donohue told Mrs. Parks that she was being terminated. Mrs. Parks began sobbing and asked Ms. Donohue why Alpharma was terminating her and Ms. Donohue told her only, "it was a business decision." Alpharma took away her company car that day and sent her home in a taxi cab. Ms. Donohue told Mrs. Parks that Alpharma would not discuss her termination with anyone, but later that afternoon after Mrs. Parks had returned to her home, she received phone calls from a physician in her sales district and from a sales representative from a competing pharmaceutical company who was actually being recruited for Mrs. Parks's position at Alpharma. [21] At the time of her termination, Mrs.

[20] After Mr. Slesinski received the medical records, he asked Mrs. Parks: "Why are you sending me your medical records?" *See* Ex. 2 (Parks Aff.), ¶ 43.

[21] Several days after her termination, Mrs. Parks's friend and then employee at Alpharma, Joann Presbitero, called Mrs. Parks and told her that another sales representative at Alpharma, Suzy Garasic, had called Ms. Presbitero to tell her that Mrs. Parks had been fired and Ms. Garasic recited exact statements to Ms. Presbitero from the termination on July 24. *See* Ex. 1 (Parks Depo.), pp. 356-357.

Parks ranked among the top five percent of Alpharma sales representatives nationally. *See* Ex. 1 (Parks Depo.), pp. 342-343, 344-349, 351-353; Ex. 2 (Parks Aff.), ¶ 44.[22]

Several months after her termination, in November 2006, Mrs. Parks spoke to James Meade who told Mrs. Parks that Pete Hill told him Hill got Mrs. Parks fired. *See* Ex. 1 (Parks Depo.), pp. 221-222.

ARGUMENT

I. PLAINTIFF DEBRA PARKS ENGAGED IN PROTECTED ACTIVITY

A. Elements of Section 3730(h) Claim

Employees seeking to bring a cause of action under § 3730(h) must meet three elements derived from the statutory text: "(1) he took acts in furtherance of a qui tam suit; (2) his employer knew of these acts; and (3) his employer [took adverse action against] him as a result of these acts." *Mann v. Heckler & Koch Defense, Inc.*, 630 F.3d 338, 343 (4th Cir. 2010).

An employee meets the first element, the "protected activity" prong when he or she satisfies the "distinct possibility" standard. *Id.* at 343-344. Under the distinct possibility standard, protected activity occurs "when an employee's opposition to fraud takes place in a context where 'litigation is a distinct possibility, when the conduct reasonably could lead to a viable FCA action, or when . . . litigation is a reasonable possibility.'" *Id.* at 344 (quoting *Eberhardt v. Integrated Design & Const., Inc.*, 167 F.3d 861, 869 (4th Cir. 1999)). An

[22] Within one week or two from her termination, defamatory statements appeared on the internet website, "Cafepharma." Those defamatory statements included that "Deb Parks is trailer trash. The only think that would be more enjoyable than watching the fired [A]pprentice in the back of the taxicab crying would have been to have a camera in the back of that taxicab when Deb Parks was sent home." Mrs. Parks testified there "was a very, very short circle of people" that knew she had been crying and that she had been sent home in a taxicab on July 24, 2006. *See* Ex. 1 (Parks Depo.), pp. 366-367; Exhibit 37 (Cafepharma Internet postings); Ex. 2 (Parks Aff.), ¶ 45.

employee's "internal reporting of false or fraudulent claims" qualifies as protected activity under Section 3730(h). *Ackley v. Int'l Bus. Machines Corp.*, 110 F. Supp. 2d 395, 400 (D.Md. 2000). If an employee's internal reports are "identifiable as disclosures of fraud or falsity," they qualify as protected activity and "a qui tam action is 'a "distinct possibility"' at the time the report is made." *Id.* at 400.

B. Mrs. Parks engaged in Protected Activity at Various Times During Her Employment at Alpharma from 2002 through July 2006

Contrary to Defendant's Motion for Summary Judgment, Plaintiff has set forth sufficient facts to establish a dispute of material fact as to whether she engaged in protected activity during her employment at Alpharma.

1. Mrs. Parks Engaged in Protected Activity with Dr. Kaplan's Switch Study

As to Dr. Kaplan's Switch Study, Mrs. Parks engaged in protected activity when she learned from Dr. Sun in approximately October 2005 that Alpharma did not want to release the results of Dr. Kaplan's Switch Study because it proved to be a failure due to the high-dose patients used in the study and the results showing a negative pharmacoeconomic impact. Mrs. Parks protested to Craig LaFay in person on December 14, 2005 and to Mike Slesinski over the phone on December 15, 2005 that the abstract poster that had been ghost-written for Dr. Kaplan did not disclose the pharmacoeconomic results of the Switch Study. *See* Ex. 1 (Parks Depo.), p. 170. Mrs. Parks also engaged in protected activity when she forwarded the final abstract poster to Kirk DuMont in May 2006 to prove that MAC had never prepared a second abstract poster and that Alpharma had in fact buried the negative pharmacoeconomic results of the study. *See* Ex. 2 (Parks Aff.), ¶¶ 18-21; Exhibit 18 (Parks 6/10/06 email).

Mrs. Parks's complaints about Alpharma hiding the negative pharmacoeconomic results of Dr. Kaplan's Switch Study could reasonably have been understood to be allegations of fraud or falsity because the abstract poster that MAC ghost wrote for Dr. Kaplan misrepresented to the medical community that patients could be successfully switched to Kadian without any negative pharmacoeconomic impact. *See Ackley*, 110 F.Supp.2d at 400. Further, burying the negative pharmacoeconomic results of the Switch Study enabled Alpharma to continue to represent to Medicaid and other Government-related formulary committees that Kadian was cost-effective and safe so that Kadian would be added to their formularies. *See* Ex. 2, ¶ 22. [23]

2. Mrs. Parks Engaged in Protected Activity with Dr. Kaplan's Conversion Method

As to Dr. Kaplan's method of converting patients to Kadian, Mrs. Parks engaged in protected activity when she discovered shortly after the August 2005 Atlanta meeting that Alpharma sales representatives did not understand Dr. Kaplan's conversion method and she notified her supervisors, Mike Slesinski and Peter Hill; who in turn, notified Craig LaFay and Kandi Marlowe. *See* Parks Depo. Ex. 55 (Parks 8/31/05 email). Mrs. Parks complained to Craig LaFay at Alpharma's headquarters in Piscataway, New Jersey in November 2005 that she did not want to be part of a sales training group that promoted Dr. Kaplan's conversion method when the sales representatives did not understand the conversion method. She also complained to Mr. Hill during field rides that sales representatives did not understand Dr. Kaplan's conversion method,

[23] Although Defendant portrays Mrs. Parks as "encouraging" the funding of Dr. Kaplan's Switch Study, in reality, the idea of **giving** Dr. Kaplan the Switch Study as an **apology** for Dr. Kaplan's falling out with Dr. Royal in April 2004 came as a direct order to Mrs. Parks from her superiors at Alpharma. Mrs. Parks's ability to maintain her employment at Alpharma **required** that she cooperate and facilitate that study, and in Dr. Royal's own words, "dog [Dr. Kaplan] on getting this trial done." Ex. 10 (Royal 8/13/04 email).

and she complained several times to Mike Slesinski over the telephone that sales representatives were simplifying the Kaplan conversion method, and thus were promoting an off-label conversion method. *See* Ex. 2 (Parks Aff.), ¶ 27. At deposition, Mrs. Parks testified when she complained to her supervisors at Alpharma about the use of Dr. Kaplan's conversion method, she used the specific words "off-label," which in the pharmaceutical industry, means "**fraudulent**." Ex. 1 (Parks Depo.), p. 474 (emphasis added). Therefore, Mrs. Parks's internal complaints regarding the Kaplan conversion method and the manner in which Alpharma sales representatives used it, could have been reasonably understood to be allegations of fraud or falsity. *See Ackley*, 110 F.Supp.2d at 400.

Finally, as to Defendant's argument that Mrs. Parks complained about "the safety of Dr. Kaplan's method" only, Mrs. Parks complained to her superiors at Alpharma that Dr. Kaplan's conversion method was both off-label and unsafe. *See* Ex. 2 (Parks Aff.), ¶ 27; Ex. 1 (Parks Depo.), p. 474 (emphasis added). [24]

3. Mrs. Parks Engaged in Protected Activity With Dr. Kaplan's Coventry Presentation in February 2006

As to the presentation that Dr. Kaplan gave to Coventry Health in February 2006, Mrs. Parks engaged in protected activity by (1) objecting that Dr. Kaplan was not an approved speaker; (2) objecting to the presentation that Matt Anderson proposed Dr. Kaplan give promoting Kadian as less prone to abuse and diversion compared to other pain medications,

[24] Contrary to Defendant's argument that Mrs. Parks "played an active role in promoting" Dr. Kaplan's conversion method, Mrs. Parks prepared the Atlanta slide presentation at the direction of Mr. LaFay. *See* Ex. 7 (LaFay Depo.), p. 258 (acknowledging Mrs. Parks could have been asked to prepare slide presentation). Dr. Sun assisted her in preparing the slide presentation and Alpharma's compliance office ultimately signed off on the slide presentation before the Atlanta conference. *See* Parks Depo. Ex. 55 (Parks 8/31/05 email).

which would have been an off-label message; and (3) objecting to paying Dr. Kaplan his honorarium through a gift certificate with her American Express card, which would have amounted to a kick-back. *See* Ex. 27 (Parks 2/4/06 email); Ex. 28 (Limbaugh Slide Presentation); Ex. 28 (Parks 2/6/06 email); Ex. 1 (Parks Depo.), p. 131.

There is no merit to Defendant's argument comparing Mrs. Parks's complaints about the proposed Coventry presentation to the facts in *Owens v. First Kuwaiti General Training & Contracting Co*., 612 F.3d 724 (4th Cir. 2010) and *Mann*, 630 F.3d 338. In *Owens*, the plaintiff relator was a foreman on a construction project and was employed by a private contractor that was performing construction work for the federal government in Baghdad, Iraq. The United States Court of Appeals for the Fourth Circuit held that the plaintiff's mere noting of "construction mistakes" to the defendant company during the work in Baghdad did not constitute protected activity, as those complaints alone did not "evince some attempt to expose possible fraud." *Owens*, 612 F.3d at 735. In *Mann*, the plaintiff, an employee of a gun manufacturer believed the defendant company had attempted to fraudulently induce the United States Secret Service into awarding the defendant a contract for production of rifles. The Fourth Circuit held, however, that the plaintiff's actions regarding the bid submission to the Secret Service amounted to "voicing *disagreement* concerning the bid *strategy*" and not as opposing fraud **because there was nothing fraudulent about the bid submission itself**. *See Mann*, 630 F.3d at 345-346.

But in this case, another employee at Alpharma, Matt Anderson, proposed that Dr. Kaplan exploit the media frenzy over Rush Limbaugh's pain medication addiction problems around 2006 to convey that Kadian was less prone to abuse and prevention than other pain medications, which would have been an off-label message and fraudulent. Contrary to Defendant's contentions, Mrs. Parks's objection over the Rush Limbaugh presentation was not

merely "an expression of a differing opinion regarding the best strategy to be successful with Coventry." Mrs. Parks knew the Rush Limbaugh presentation was off-label and illegal; she objected to it and, ultimately, Dr. Kaplan did not use the presentation.

Moreover, Mrs. Parks's objections that Dr. Kaplan was not an approved speaker and her refusal to pay Dr. Kaplan his honorarium with her American Express card constitutes protected activity because paying Dr. Kaplan through a gift certificate would have amounted to a kickback to Dr. Kaplan.[25] In May 2003, the Office of the Inspector General ("OIG") released a formal guidance to pharmaceutical manufacturers, identifying several marketing practices that run a high risk of violating the Anti-Kickback Statute. *See OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731 (May 5, 2003) (the "2003 Guidance"). The 2003 Guidance cites the PhRMA Code as a useful guide in interpreting the Anti-Kickback rules.[26] *Id.* at 23737. Specifically, the PhRMA Code provides that "[p]ayments in cash or cash equivalents (**such as gift certificates**) should **not** be offered to healthcare professionals either

[25] The federal Anti-Kickback Act, 42 § 42 U.S.C. § 1320a-7(b)b, prohibits any person or entity from providing or accepting "anything of value" to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. *See* 42 U.S.C. § 1320a-7(b)b.

[26] PhRMA is the Pharmaceutical Research and Manufacturers of America, a voluntary association of the country's leading pharmaceutical companies. Effective July 1, 2002, PhRMA adopted a new marketing code, entitled, "Code on Interactions with Healthcare Professionals" (the "PhRMA Code"). The PhRMA Code provides guidelines for how sales representatives and others involved in marketing pharmaceuticals should interact with healthcare professionals. A copy of the 2002 PhRMA Code is attached hereto as Exhibit 38 and is publicly available at: http://www.temple.edu/medicine/cme/documents/PHARMA.pdf

directly or indirectly . . . ." *See* Exhibit 38 (2002 PhRMA Code, § 7(d), p.5) (emphasis added).[27]

The cases Defendant cites in support of their argument concerning Mrs. Parks's objections to paying Dr. Kaplan through a gift certificate are all inapposite because none of them involve the Anti-Kickback Statute. Those cases, none of which are even binding authority on this Court, do not address the issue of whether paying an untrained, unapproved physician speaker compensation through a gift certificate would amount to a kickback.[28]

In sum, Mrs. Parks's complaints concerning Dr. Kaplan's Coventry presentation in February 2006 coupled with her complaints and refusal to pay Dr. Kaplan through a gift certificate purchased with her American Express card could reasonably be understood to be allegations of fraud or falsity. *See Ackley*, 110 F.Supp.2d at 400.

4. Mrs. Parks Engaged in Protected Activity With the Alcohol Clinical Trials

The undisputed evidence in this case demonstrates that while Alpharma's in vivo clinical trials were pending from at least October 2005 through the time of Mrs. Parks' termination in July 2006, Alpharma promoted Kadian on the basis that it was safe when taken with alcohol, even though it had no scientific proof to assert that assertion. *See* Ex. 3 (Stauffer Depo.), pp. 95, 98-99 (until Alpharma completed its study into whether Kadian dose-dumped with alcohol, which it did not complete until **February 2007**, Alpharma's sales force could not "tout or

[27] Additionally, under the "Frequently Asked Questions" section of the PhRMA Code, it states that inviting a physician to hear an educational presentation about a new drug at a nearby bookstore café and giving the physician "a gift certificate for books in the amount of $30" does **not** conform to the PhRMA Code because "an open-ended gift certificate is a cash equivalent." Ex. 38 (PhRMA Code, at Question "f", p. 7).

[28] *See Kennedy v. Aventis Pharm., Inc.*, No. 03 CV-2750, 2008 WL 4371323 (N.D.Ill. Feb. 11, 2008); *Heater v. Holy Cross Hosp., Inc.*, 510 F. Supp.2d 1027 (S.D. Fla. Feb. 15 2007); *Longest v. Dyncorp*, No. 603CV816ORL31JGC, 2006 WL 47791 (M.D.Fla. Jan. 9, 2006).

promote" Kadian on the basis that it was safe when taken with alcohol); Ex. 7 (LaFay Depo.), pp. 235-236, 244 (Alpharma marketed Kadian on the basis that Kadian could be taken with alcohol without any adverse effect after Ligand issued its "Dear Doctor" letter concerning the addition of a black box label warning on Avinza regarding dose-dumping, in October 2005).

During her employment at Alpharma, Mrs. Parks had direct contact both with Dr. George Wagner, Dr. Stauffer and Dr. Sun – who were in charge of handling the alcohol clinical trials – concerning the alcohol studies. Mrs. Parks in fact provided them with the Purdue Pharma monograph concerning its clinical trials on Palladone. After Mrs. Parks learned from James Mead that Kadian had a dose-dumping effect in approximately February 2006, she immediately contacted Dr. Sun about that statement. Dr. Sun did not deny Mr. Mead's statement; rather, Dr. Sun told Mrs. Parks to "**stop asking questions**." Mrs. Parks then complained to Ron Warner, Vice President of Alpharma, Dr. Stauffer, and Peter Hill that Alpharma was conveying to physicians that Kadian had no risk of dose dumping when consumed with alcohol when the clinical trials were still pending.

Contrary to Defendant's argument in their Motion for Summary Judgment, Mrs. Parks's complaints to Mr. Warner, Dr. Stauffer and Peter Hill constitute protected activity because Mrs. Parks was complaining about company conduct – the false promotion of Kadian as superior to other opioids because it had no risk of adverse effects from co-ingestion with alcohol – that involved an **objectively reasonable possibility** of an FCA action. *Mann*, 630 F.3d at 344-45; *Ackley*, 110 F.Supp.2d at 400. As Dr. Stauffer testified, it was not until February 2007 – more than 6 months after Mrs. Parks's termination – that Alpharma learned that Kadian showed no risk of dose-dumping, (*see* Ex. 3 (Stauffer Depo.), p. 95), yet Alpharma had been falsely

promoting Kadian as safe with alcohol from at least October 2005 through July 2006. *See* Ex. 7 (LaFay Depo.), pp. 235-236, 244.

5. Mrs. Parks Engaged in Protected Activity When She Objected to Promoting Kadian as Less Prone to Abuse and Diversion Compared to Other Pain Medications

Mrs. Parks engaged in protected activity when she complained to Dr. Stauffer and Mr. LaFay in June 2006 that sales representatives were using Alpharma's internet surveillance study to convey to physicians that Kadian had less abuse and diversion potential compared to other opioids. Dr. Stauffer himself testified at deposition that assuming Mrs. Parks did complain to him that day that sales representatives were using the internet surveillance report in detailing Kadian as less prone to abuse and diversion, he would have agreed with Mrs. Parks that the study should not be used in such a manner. *See* Ex. 3 (Stauffer Depo.), p. 83. [29] Accordingly, Mrs. Parks's internal complaints about the use of the internet surveillance study in detailing Kadian could have been reasonably understood to be allegations of fraud or falsity. *See Ackley*, 110 F.Supp.2d at 400.

II. ALPHARMA KNEW OF MRS. PARKS'S PROTECTED ACTIVITY

A. Notice Requirement

The second element of a § 3730(h) claim is that the "employer knew of" the plaintiff's protected activity. *Mann*, 630 F.3d at 343. An employer may be put on notice by "any action which a factfinder reasonably could conclude would put the employer on notice that litigation is a reasonable possibility. Such actions would include, *but are not limited to*, characterizing the

[29] Dr. Stauffer testified it is "possible" that he had a conversation with Mrs. Parks in June of 2006 in which she expressed her concern that sales representatives were using the internet surveillance study in sales detailing for Kadian. *See* Ex. 3 (Stauffer Depo.), p. 75.

employer's conduct as illegal or fraudulent or recommending that legal counsel become involved." *Eberhardt*, 167 F.3d at 868-869 (emphasis added). The *Eberhardt* "notice" standard applies specifically to an employee who has been tasked with the "internal investigation of fraud," which does not apply in this case as Mrs. Parks's job duties at Alpharma never entailed investigating fraud. *See id.* Ex. 2 (Parks Aff.), ¶ 51. Therefore, the Eberhardt "notice" standard is a slightly higher standard than would apply in this case. *See Mann v. Heckler & Koch Defense, Inc.*, 2008 WL 4551104, *5 (E.D.Va. Oct. 7, 2008) (recognizing that where the Plaintiff is not tasked with the internal investigation of fraud, the *Eberhardt* standard "remains relevant and, if anything, implies that Plaintiff would need to meet *a less demanding standard, not a higher one*." (emphasis added)).

As the Court in *Ackley* explained: "the same reports of fraudulent or false [conduct by a company] that could be deemed to represent a 'distinct possibility' of a qui tam suit for purposes of satisfying the 'in furtherance' requirement" can "also establish a 'reasonable possibility' of such a suit" for purposes of the proving notice to the employer. "In both cases, the question is whether what [plaintiff] told [her] superiors was sufficiently suggestive of fraud or falsity" that the defendant company "should have reasonably understood the possible follow-on of qui tam litigation." *Ackley*, 110 F.Supp.2d at 401.

B. Alpharma Had Notice of Mrs. Parks's Protected Activity

Contrary to Defendant's argument in its Motion for Summary Judgment, Mrs. Parks has sufficient evidence to establish an issue of material fact as to whether Alpharma knew of her protected activity.

First, Defendant's assertion that "[i]t is undisputed that plaintiff did not characterize Alpharma's conduct as illegal or fraudulent . . . verbally" is disingenuous considering in the very

deposition testimony Defendant's cite in their memorandum, Mrs. Parks testified, with respect to Dr. Kaplan's conversion method, she complained to others at Alpharma that it was "off-label," which in the pharmaceutical industry means "fraudulent" or "illegal." *See* Ex. 1 (Parks Depo.), p. 474. Moreover, Defendant fails to cite any authority (nor is Plaintiff aware of any) for the proposition that a plaintiff such as Mrs. Parks, who had no role in investigating fraud at Alpharma, must use the words "illegal" or "fraudulent" to satisfy the notice requirement.

As demonstrated more fully above, Mrs. Parks's complaints to her superiors at Alpharma were sufficiently suggestive of fraud or falsity that Alpharma should have reasonably understood the possible follow-on of qui tam litigation. With respect to the Switch Study, Mrs. Parks objected to Dr. Sun when he told her that Dr. Kaplan's Switch Study was a failure and Alpharma wanted to disassociate itself from high-dose morphine patients. Mrs. Parks told Craig LaFay in person on December 14, 2005 in Piscataway, New Jersey that she was very unhappy that Alpharma had decided to hide the pharmacoeconomic results of the Switch Study and that Dr. Kaplan had performed the study in good faith. Mrs. Parks also told Mike Slesinski on the phone on December 15, 2005 that she did not like that Alpharma had decided to hide the pharmacoeconomic results of the Switch Study. Mrs. Parks also complained to Mr. Slesinski that MAC had ghost-written the Switch Study for Dr. Kaplan. *See* Ex. 1 (Parks Depo.), p. 170. Mrs. Parks also discussed with Kirk DuMont and Mike Slesinski whether Alpharma would be producing a second abstract that showed the pharmacoeconomic results of the Switch Study, and Mr. DuMont and Mr. Slesinski assured Mrs. Parks MAC would produce a second abstract. After Mrs. Parks learned that MAC had produced one poster abstract only – which did not disclose the pharmacoeconomic results of the Switch Study – Mrs. Parks forwarded a copy of the final poster

abstract to Mr. DuMont to prove that no second abstract poster had been produced. *See* Ex. 2 (Parks Aff.), ¶¶ 18-21; Ex. 18 (Parks 6/10/06 email).

As to the Kaplan conversion method, on August 31, 2005, Mrs. Parks complained to Mr. Slesinski and Mr. Hill that she was being overwhelmed with the number of calls from sales representatives who had questions about the conversion method, and she suggested Alpharma set up a conference call. *See* Ex. 1 (Parks Depo.), pp. 471-472, 496; Parks Depo. Ex. 55 (Parks 8/31/05 email). Craig LaFay was notified about Mrs. Parks's request to set up a conference call. In November 2005, Mrs. Parks spoke to Mr. LaFay in person at Alpharma's headquarters in Piscataway, New Jersey and she told him she did not want to be part of a sales group that promoted Kaplan's conversion method when sales representatives did not understand it. She also complained to Peter Hill and Mike Slesinski that sales representatives did not understand the Kaplan conversion method, and she spoke to Mr. Slesinski several times over the telephone explaining that sales representatives were simplifying the conversion method and thus were promoting an off-label conversion method. *See* Ex. 2 (Parks Aff.), ¶ 27.

As to the Coventry presentation, Mrs. Parks sent emails to Pete Hill and Mike Slesinski objecting to Matt Anderson's proposed off-label message for the Coventry presentation. She protested to Mike Slesinski that Dr. Kaplan was not an approved speaker, and she later complained and objected to Pete Hill when he instructed her to pay Kaplan's honorarium with her American Express, which Mr. LaFay also knew about.

As to Alpharma's alcohol clinical trials, after learning from James Meade on February 9, 2006 that the clinical trials showed Kadian dose-dumped, Mrs. Parks spoke both to Ron Warner and Dr. Stauffer and stated that Alpharma appeared to be using the delay before receiving the clinical trial results as an advantage in marketing that Kadian had no risks of adverse events

when co-ingested with alcohol. *See* Ex. 1 (Parks Depo.), pp. 419, 426. She also complained to Mr. Hill during sales rides about the alcohol absorption study, (*id.* at p. 126), and she complained to Mr. Hill that he should not be marketing Kadian as safe with alcohol. *See* Ex. 2 (Parks Aff.), ¶¶ 37-40.

Finally, Mrs. Parks spoke to Mr. LaFay and Dr. Stauffer in person in June 2006 and stated she was concerned that sales representatives were using Alpharma's internet study to market Kadian as less prone to abuse and diversion, which Mr. LaFay and Dr. Stauffer knew at the time would have been an off-label message. *See* Ex. 2. (Parks Aff.), ¶ 42; Ex. 7 (LaFay Depo.), p. 122; Ex. 3 (Stauffer Depo.), p. 28, 83.

In sum, Mrs. Parks's statements to her superiors at Alpharma were sufficiently suggestive of fraud or falsity that Alpharma should have reasonably understood the possible follow-on of a qui tam litigation. *See Ackley*, 110 F.Supp.2d at 400-401.

III. ALPHARMA RETALIATED AGAINST MRS. PARKS BECAUSE OF HER PROTECTED ACTIVITY

The final element of a Section (h) claim is that the employer took adverse action against the employee because of the protected activity. *See Mann*, 630 F.3d at 343. In other words, the third element requires proof of a "causal connection" between the protected activity and the employer's adverse employment action. *Gibson v. Marjack Co.*, 718 F. Supp.2d 649, 653 (D. Md. 2010); *see also Glynn v. Edo Corp.*, 536 F. Supp. 2d 595, 612 (D. Md. 2008). "To establish a causal connection between a protected activity and an adverse action, a plaintiff must prove that the protected activity preceded the adverse action and that the employer knew the employee engaged in a protected activity." *Gibson*, 718 F.Supp.2d at 655. Additionally, the United States District Court for the District of Maryland has recognized "temporal proximity" between a

plaintiff's protected conduct and the adverse employment acts, including the employee's ultimate discharge, as a basis for establishing causation. *See Glynn*, 536 F.Supp.2d at 612; *see also Marlar v. BWXT, LLC*, No. 3:04-CV-415, 2009 WL 2195424, *5 (E.D. Tenn. July 23, 2009).

In this case, there is no dispute that Mrs. Parks's alleged protected activity preceded her termination on July 24, 2006. For the reasons already discussed in Sections I and II of this Memorandum, Mrs. Parks has sufficient evidence to establish at least a material issue of fact that Alpharma had notice of her protected activity before her termination.

The temporal proximity between Mrs. Parks's protected activity and her termination further establishes causation. With respect to the Kaplan conversion method, Mrs. Parks complained to Mr. LaFay regarding the Kaplan conversion method at Alpharma's home office in November 2005 approximately eight months before her termination. Mrs. Parks complained to Craig LaFay and Mike Slesinski in December 2005 about Alpharma deciding to bury the pharmacoeconomic results of the Switch Study. Dr. Kaplan's Coventry presentation occurred on February 6, 2006 and the dispute as to how Alpharma would pay Dr. Kaplan for that presentation extended at least into late March 2006, approximately four months before Mrs. Parks's termination.

Also in February 2006, Mrs. Parks spoke to Dr. Sun and asked about James Meade's statement that Kadian dose-dumped, to which Dr. Sun responded to Mrs. Parks: "stop asking questions" and "mind your own business." In late February 2006, Mrs. Parks spoke to Ron Warner regarding the alcohol clinical trials in Amelia Island, South Carolina and around that same time, Mrs. Parks complained to her manager, Pete Hill, during field rides that he should not be marketing Kadian as safe with alcohol.

Finally, Mrs. Parks spoke to Craig LaFay and Dr. Stauffer about use of the Alpharma internet study to market Kadian as late as June 2006. On June 10, 2006, less than two months before her termination, after learning that MAC had not produced a second poster abstract for Switch Study, Mrs. Parks forwarded Kirk DuMont the final poster abstract that had been presented proving no second abstract poster had been produced with the pharmacoeconomic results of the Switch Study.

In addition to the temporal proximity between Mrs. Parks's protected activity and her termination, Dr. Sun's statement in February 2006 that Mrs. Parks should "stop asking questions" with respect to the alcohol clinical trials and "mind [her] own business," and Pete Hill's retaliatory behavior that started in approximately November or December 2005 and lasted through at least March 2006 further establish causation. *See Glynn*, 536 F.Supp.2d at 612; *Marlar*, 2009 WL 2195424 at *5.

IV. ALPHARMA'S PROFERRED NON-RETALIATORY REASON FOR TERMINATING MRS. PARKS IS PRETEXTUAL

Although Defendant has proffered a non-retaliatory reason for terminating Mrs. Parks, Mrs. Parks may establish pretext by showing "(1) that the proffered reasons had no basis in fact; (2) that the proffered reasons did not actually motivate the employer's action; or (3) the proffered reasons were insufficient to motivate the employer's action." *Marlar*, 2009 WL 2195424, *5 (quoting *Manzer v. Diamond Shamrock Chems. Co.*, 29 F.3d 1078, 1084 (6th Cir.1994)).

A. Alpharma's Proffered Reason for Terminating Mrs. Parks Has No Basis in Fact

With respect to the first showing of pretext, it "consists of evidence that the proffered bases for the plaintiff's [adverse employment action] never happened." *See id.* In this case,

Defendant's proffered bases for its decision to terminate Mrs. Parks – including that Mrs. Parks complained about her merit increase for 2005, she spread "rumors" that Pete Hill and Sheila Swanson were having a romantic affair, and that she failed to keep the facts of the Human Resources investigation confidential – simply did not happen. *See* Ex. 2 (Parks Aff.), ¶ 46.

According to the affidavit of Regina Donohue attached to Defendant's motion, Ms. Donohue first started investigating whether Mrs. Parks had complained about her merit increase for 2005 on March 8, 2006. But that is impossible because Mrs. Parks did not learn about her 2005 merit increase until she received a telephone call from Pete Hill on **March 16, 2006**.[30] *See* Ex. 2 (Parks Aff.), ¶ 47. Exhibit 13 attached to the declaration of Regina Donohue, which purports to be type-written notes of Regina Donohue, states "Pete [Hill] had informed his District of their merit increases on **March 16th**." *See* Decl. of Regina Donohue, Ex. 13 (emphasis added). Further, Mrs. Parks was not upset about her 2005 merit increase. In mid-late March 2006, Mrs. Parks had just returned from the National Sales Meeting in Amelia Island where, in recognition of her being in the "Circle of Excellence," she received a $5,000 increase in base salary, in addition to her merit increase of $3600, resulting in a salary increase of $8600. Additionally, Mrs. Parks was planning to travel and did travel to Maui, Hawaii in late March 2006 with her family, which Alpharma paid for as another reward for her outstanding sales performance. Therefore, it is preposterous for Defendant to contend that Mrs. Parks complained

[30] Mr. Hill informed Mrs. Parks that he was gave her a 4.5% merit increase, rather than a 5% merit increase. Mrs. Parks's salary in March 2006 was approximately $80,000, and therefore the difference between a 4.5% increase versus a 5% increase amounts to $400. *See* Ex. 2 (Parks Aff.), ¶ 47.

in March 2006 over her merit increase considering all the other perks she received.[31] *See* Ex. 2 (Parks Aff.), ¶ 48.

As to the allegations that Mrs. Parks was "spreading rumors" that Pete Hill and Sheila Swanson were having an affair, Mrs. Parks testified she "never, never did that." Ex. 1 (Parks Depo.), pp. 231, 212. Further, Mrs. Parks denied telling employees at Alpharma that Hill and Swanson had an "unprofessional relationship," that there was "funny business" going on between them, or that they were "having a romantic affair." *Id.* at p. 299. Further, Mrs. Parks never engaged in any "negative gossip," nor did she criticize any member of Alpharma management during this time period either. *See* Ex. 2 (Parks Aff.), ¶ 49.

When Mrs. Parks met with Regina Donohue and George Rose in May 2006, Ms. Donohue asked Mrs. Parks whether she had ever said that Hill and Swanson were having an affair, and Mrs. Parks "vehemently denied it" and was "outraged" about the allegations. *See* Ex. 1 (Parks Depo.), p. 305.[32] After that meeting, Elissa Halperin called Mrs. Parks's counsel, Robert C. Morgan, Esq., and told him Alpharma had completed the investigation and the allegations were not corroborated and nothing would come of the investigation. *See* Ex. 35 (Morgan Aff.). Mrs. Parks thereafter kept the investigation confidential and did not discuss the

[31] What actually occurred sometime in mid-late March 2006 is another sales representative, Suzy Garasic, called Mrs. Parks to complain about her compensation. Mrs. Parks forwarded Ms. Garasic's complaint to Mr. Slesinski, and Mrs. Parks never told anyone or complained to anyone about her merit increase for 2005. *See* Ex. 1 (Parks Depo.), p. 316; Ex. 2 (Parks Aff.), ¶ 48.

[32] Mrs. Parks testified that when Regina Donohue called her in May 2006 to tell her to come in for a meeting at Alpharma's headquarters, Mrs. Parks asked Ms. Donohue if Pete Hill had to attend, and Ms. Donohue responded, no, "[b]ecause it would not be appropriate **as he made the allegations**." Ex. 1 (Parks Depo.), p. 302 (emphasis added).

investigation with any sales representatives at the meeting in Orlando, Florida in June, 2006.[33] *See* Ex. 1 (Parks Depo.), p. 338.

Although Alpharma told Robert Morgan on May 15, 2006 that nothing would come of the HR investigation, several days before, on May 9, notes of a meeting between Regina Donohue, Elissa Halperin, and Kritine Feher suggest Alpharma had already started to build its case against Mrs. Parks. At the top of those notes, it states: "**DP – immediate offensive strike**." *See* Decl. of Donohue, Ex. 23 (emphasis added). The notes also refer to several "witnesses" and whether they "will they stand by their [statements]." Then, the purported "last straw" as to Mrs. Parks's employment at Alpharma occurred when Candice Ashley allegedly reported that Mrs. Parks had approached her on June 13, 2006 and discussed the details of the HR investigation. *See* Decl. of Donohue, Ex. 30. Yet Mrs. Parks denies that she had the conversations with Candice Ashley described in Exhibit 30 attached to Regina Donohue's Declaration. There is no evidence that Alpharma made any attempt whatsoever to confirm the report of Candice Ashley with Mrs. Parks – and Alpharma never did. Instead, by late June or early July, Alpharma purportedly decided just to terminate Mrs. Parks. *See* Ex. 2 (Parks Aff.), ¶ 50.

In sum, Alpharma's proffered basis for terminating Mrs. Parks is littered with factual inaccuracies and has no basis in fact.

[33] Mrs. Parks testified that at the Orlando meeting other Alpharma sales representatives came up to Mrs. Parks and told her they heard she had almost gotten fired, but Mrs. Parks told them she did not know anything about it. *See* Ex. 1 (Parks Depo.), p. 338.

B. Alpharma's Proffered Reasons Are Insufficient to Motivate Alpharma's Termination of Plaintiff

Even assuming, *arguendo*, Alpharma's proffered reasons for terminating Mrs. Parks has some basis in fact, those proffered reasons were insufficient to motivate Alpharma's termination of Mrs. Parks. At the time of her termination, Mrs. Parks was ranked nationally among the top five percent of Alpharma sales representatives, she had earned "Representative of the Year" in 2004, and she was the number two Alpharma representative in 2005. In February 2006, she had earned Alpharma's "High Five" award, which is based on employee behavior rather than sales volume. *See* Ex. 2, ¶ 4. Alpharma's contention that it fired Mrs. Parks because she failed to keep the HR investigation confidential is insufficient to support the termination considering Mrs. Parks's extraordinary success at Alpharma.

Moreover, in an email from Regina Donohue to Elissa Halperin dated June 14, 2006, Ms. Donohue relayed information that purportedly came from Pete Hill that "[a] rep from DPs [Deb Parks's] district told Pete that DP came up to her yesterday at the meeting and asked if she heard what was going on." Exhibit 39 (Donohue 6/14/06 email). At the conclusion of the email, Ms. Donohue writes: "Thinking if this is confirmed that **a written warning might be in order? Last chance warning? Your thoughts?**" *Id.* (emphasis added). Based on that email, Alpharma's Director of Human Resources construed the allegations that Mrs. Parks had breached the confidentiality agreement – assuming confirmation of those allegations – as requiring merely a written warning, **not** termination.

Therefore, Alpharma's proffered reasons for terminating Mrs. Parks were insufficient to motivate Mrs. Parks's termination. *See Marlar*, 2009 WL 2195424, *5-6.

V. MRS. PARKS DID NOT ADMIT THAT SHE WAS TERMINATED FOR REASONS OTHER THAN IN RETALIATION FOR PROTECTED ACTIVITY

In contending that that Plaintiff "effectively admits she was terminated for reasons" other than her protected activity, Defendant cites a part of Mrs. Parks's deposition transcript where Defendant's counsel asked Mrs. Parks if a defamation lawsuit Mrs. Parks filed against two former co-workers in May 2007 contained "true and accurate" allegations. *See* Ex. 1 (Parks Depo.), pp. 211-220. Contrary to Defendant's argument, Mrs. Parks never admitted at deposition she was terminated for reasons other than in retaliation for protected activity. Rather, in response to Defense counsel's questioning regarding that lawsuit, Mrs. Parks testified she filed the lawsuit based on "what the company [Alpharma] was telling me *at the time*. . . . I was up against a statutory deadline and I wanted to be able to assure the truth would come out and that I would have the opportunity to . . . assert all my rights." *Id.* at p. 220 (emphasis added). Accordingly, there is no merit to Defendant's contention that based on Mrs. Parks deposition testimony and her allegations in that earlier lawsuit, Mrs. Parks actually "believes" she was in fact terminated because of the false allegations concerning her conduct by other employees.

VI. ALPHARMA RETALIATED AGAINST MRS. PARKS WHEN IT BROADCASTED THE NEWS OF HER TERMINATION

Immediately after Mrs. Parks's termination, the news of her termination spread rapidly throughout Alpharma and eventually into the pharmaceutical marketplace. *See* Ex. 1 (Parks Depo.), pp. 351-367. On July 24, 2006, Alpharma employee Felicia Harrison sent an email to 20 other Alpharma employees (including LaFay and Donohue) notifying them of Mrs. Parks's termination. *See* Exhibit 40 (Harrison 7/24/06 email). Mrs. Parks, however, had the expectation that Alpharma would keep the fact of her termination confidential. On the very afternoon on the day of her termination Mrs. Parks received telephone calls from a physician in her sales district

and from a sales representative from a competing pharmaceutical company who was actually being recruited for Mrs. Parks's now vacant position at Alpharma. Mrs. Parks later heard from other sales representatives at Alpharma who recited exact statements from Mrs. Parks's termination, even though Ms. Donohue and Mr. LaFay had been the only Alpharma employees present during the termination. *See* Ex. 1 (Parks Depo.), pp. 351-353, 356-357. Therefore, contrary to Defendant's argument in its motion for summary judgment, there is sufficient evidence to establish an issue of material fact that Alpharma spread the news of Mrs. Parks's termination to embarrass her in the pharmaceutical marketplace and in retaliation for her protected activity.

VII. CONCLUSION

For all of the foregoing reasons, it is respectfully requested that this Honorable Court enter an order denying Defendant's motion for summary judgment.

Respectfully submitted,

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